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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,389	10/29/2003	Lawrence T. Boni	TRA-00801	6398

25181 7590 10/10/2007

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,389	BONI ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 8-2-07 is acknowledged.

Claims included in the prosecution are 1-30.

In view of amendments, the 112 rejections, 102 rejections over Lagace, and Gonda have been withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 6, 17, 18, 21-26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Deol et al (Biochimica et Biophysica Acta (1997).

Deol teaches the treatment of tuberculosis in mice by the administration of liposomal formulations containing ant tubercular drugs rifampicin and isoniazid. The liposomes contain cholesterol and the administration is once (abstract, 2,1 to 3.9).

3. Claims 1-4, 6, 9-11, 14-18, 21-26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hersch (5,756,120).

Hersch teaches liposomal formulations containing amino glycosides for the treatment of the infections caused by Pseudomonas, M. avium and M. tuberculosis (col. 1, lines 38-62; col. 4, line 33 through col. 8, line 13, Examples and claims).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersch cited above.

Hersch as pointed out above, teaches liposomal formulations containing amino glycosides for the treatment of the infections caused by Pseudomonas, M. avium and M. tuberculosis (col. 1, lines 38-62; col. 4, line 33 through col. 8, line 13, Examples and claims). What is lacking in Hersch is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results. Hersch does not teach that the host infected with this organism has also cystic fibrosis. However, since the composition of Hersch is effective against this organism, it would have been obvious to one of ordinary skill in the

art that the composition would be effective against this organism irrespective of whether the patient is suffering from other conditions.

6. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonda et al (US 2005/0019926).

Gonda et al while disclosing liposomal formulations containing amino glycosides. According to Gonda et al, such formulations can be used for treatment of bacterial diseases in cystic fibrosis patients. The amino glycosides include tobramycin and amikacin. The composition is administered by pulmonary route (0011, 0027, 0060-0066, 0070 and 0089). What is lacking in Gonda et al is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that Gonda teaches nucleic acid complexed cationic amino glycosides and that is a different species and the skilled artisan would not be motivated by Gonda to provide a method of treating pulmonary infections using liposomal/complexed anti-infective. This argument is not persuasive since instant claims do not exclude nucleic acids and since the same antibiotics are taught by Gonda, one of ordinary skill in the art would expect these antibiotics to treat the same infections. With regard to the dosing argued by applicant, the examiner points out that the dosing depends on many factors and applicant has not shown any unexpected results.

7. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lagace (5,662,929) in combination with Deol or vice versa.

Lagace teaches that chronic lung infection due to P. aeruginosa is a major cause of morbidity and mortality in patients with cystic fibrosis. According to Lagace P aeruginosa colonizes more than 90 % cystic fibrosis adolescents. Lagace teaches the encapsulation of amino glycosides in liposomes for the treatment of P. aeruginosa infections. One of the modes of administration taught by Lagace is aerosol (abstract, col. 3, line 7 through col. 6, line 16; col. 7, line 40 through col. 8, line 15; Examples). What is lacking in Lagace is the inclusion of cholesterol in the liposomes. What is also lacking in Lagace is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

The teachings o Deol have been discussed above. Deol further teaches that cholesterol-containing liposomes are more stable (page 169, col. 2 through 170, col. 1).

As pointed out above, the reference of Hersch shows the routine use of cholesterol in liposomes for the treatment of infections.

The use of cholesterol in the liposomes of Lagace would have been obvious to one of ordinary skill in the art since Deol teaches that cholesterol containing liposomes are more stable. Alternately the use of amino glycosides in the liposomes of Deol would

have been obvious to one of ordinary skill in the art since the liposomes taught by Deol successfully deliver the antibiotics at the site of the infection and therefore, one would encapsulate any antibiotic to treat a disease causing bacteria which is susceptible to that antibiotic.

8. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lagace (5,662,929) in combination with Hersch (5,756,120).cited above.

Lagace teaches that chronic lung infection due to P. aeruginosa is a major cause of morbidity and mortality in patients with cystic fibrosis. According to Lagace P aeruginosa colonizes more than 90 % cystic fibrosis adolescents. Lagace teaches the encapsulation of amino glycosides in liposomes for the treatment of P. aeruginosa infections. One of the modes of administration taught by Lagace is aerosol (abstract, col. 3, line 7 through col. 6, line 16; col. 7, line 40 through col. 8, line 15; Examples). What is lacking in Lagace is the inclusion of cholesterol in the liposomes. What is also lacking in Lagace is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

As pointed out above, the reference of Hersch shows the routine use of cholesterol in liposomes for the treatment of infections.

The use of cholesterol in the liposomes of Lagace would have been obvious to one of ordinary skill in the art with a reasonable expectation of success, since Hersch shows the routine use of cholesterol in liposomes for the treatment of infections.

Double Patenting

9. Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 74-76, 78-84, 86-87, 94-95, 98-102 and 105-108 of copending Application No. 10/383,173 by itself or in combination with Lagace cited above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both are drawn to a method of treatment of diseases caused by the same organisms using the same liposomal compositions containing the same active agents. Instant claims recite the limitation that the patients having these organisms in addition suffer from cystic fibrosis. Since the active agents used are for the treatment of the infective disease itself and not the additional disease conditions the patient is suffering from, it would have been obvious to one of ordinary skill in the art to use the compositions irrespective of other disease conditions the patient is suffering from. One of ordinary skill in the art would be motivated to treat the same infective disease in cystic fibrosis patients since the reference of Lagace teaches that 90 % of cystic fibrosis patients are infected with P

aeruginosa and that liposomal compositions containing the antibiotics could be used for the treatment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained in view of applicant's request for holding the rejection in abeyance.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK